



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

100

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,753	08/22/2001	Frank Himmelsbach	5/1301	8721
28505	7590	04/20/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,753	HIMMELSBACH ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-8 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 are pending in the application.

This action is in response to applicants' amendment filed December 17, 2003.

Claims 1, 2, 6 and 7 have been amended and claim 8 is newly added.

Response to Amendment

Applicant's amendments filed December 17, 2003 have been fully considered with the following effect:

1. With regards to the rejection as being drawn to an improper Markush group of the last office action, the applicant's stated that claim 1 has been amended to recite a compound where X is a nitrogen atom. However, this is not so.

Claims 1, 5-7 and newly added claim 8 are rejected as being drawn to an improper Markush group, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 6 and 7, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that claim 6 is directed to a pharmaceutical composition, not to a method of treating a disease. However, MPEP 2164.01(c) states: When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. Hence, claim 6 is included in the rejection under 35 U.S.C. § 112, first paragraph.

With regards to claim 7 the applicants' stated the Patent and Trademark Office has the initial burden of challenging a presumptively correct assertion of utility; evidence must be presented that those of skill in the art would doubt the disclosure. Plowman et

Art Unit: 1624

al., DN&P cited herein teaches that each specific receptor is associated with specific cancers, i.e. met is associated with thyroid and gastric carcinoma, PDGFR α is associated with ovarian cancer, PDGFR β is associated with astrocytoma, restenosis, atherosclerosis, renal and hepatic fibrosis, chronic dermal ulcers, etc. Plowman exhibits the association of specific clinical indications or diseases with the various receptor tyrosine kinases and thus the scope of the method claims are not adequately enabled solely based on its tyrosine kinase inhibition provided in the specification.

Claims 6 and 7 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejection labeled a) of the last office action, which is hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled b), c) and d), the applicants' amendments and remarks have been fully considered but they are not found persuasive.

b) The applicants stated that claim 1 has been amended such that the paragraph of lines 25 and 26 on page 52 must be read together with the paragraph above. However, changing the format of the claim does not change the fact that there are two different definitions for the variable Y. Clear delineation is needed to distinguish one from the other. (Claim 1 and 5-8)

c) The applicants stated that the cited limitation has antecedent basis in claim 1 and that the support for a piperidino group substituted in the 4-position by a R₆S group can be found in the definition where "a pyrrolidino, piperidino or hexahydroazepino group substituted by the group R₆, wherein R₆ denotes a 2-oxo-tetrahydrofuranyl, 2-oxo-tetrahydropyranyl, 2-oxo-1,4-dioxanyl or 2-oxo-4-(C₁₋₄-alkyl)-morpholinyl group optionally substituted by one or two C₁₋₂-alkyl groups,". The applicants submit that since no position is given for the substitution in claim 1, any possible position is included in the definition.

However, there is no antecedent basis for the substitution of R₆ through the sulfur atom. (Claim 2)

d) The applicants stated that one skilled in the art would have no problem understanding what is being claimed. However, as pointed out in the response to the enablement rejection, there are specific clinical indications or diseases with the various receptor tyrosine kinases. (Claim 7)

Claims 1, 2, 5-7 and newly added claim 8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

4. With regards to the obviousness-type double patenting rejection of claims 1, 2 and 5-7 over the claims of U.S. Patent No. 6,403,580, the applicants' filing of a terminal disclaimer is sufficient to overcome the obviousness-type double patent rejection, which is hereby **withdrawn**.

5. With regards to the obviousness-type double patenting rejection of claims 1-7 over the claims of copending Application No. 09/914,323, the applicants' filing of a terminal disclaimer is sufficient to overcome the obviousness-type double patent rejection, which is hereby **withdrawn**.

In view of the amendment dated December 17, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claim 2 is vague and indefinite in that it is not known what is meant by sulphenyl in the nomenclature of the substituent on the piperazino group, i.e. page 12, line 5.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 1624

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/353,616. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the instant invention is embraced by the claims of 10/353,616 where R_c is as defined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 09/934,753

Page 7

Art Unit: 1624

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Brenda Coleman".

Brenda Coleman
Primary Examiner Art Unit 1624
April 18, 2004